K12186

AUG 2 2012

PREMARKET NOTIFICATION [510(k)] Summary

This Summary of Safety and Effectiveness is prepared in accordance with 21 CFR Part 807.92(c).

1. Company Name:

Submitter: Chison Medical Imaging Co., Ltd.

No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

Contact:

Ms. Ruoli Mo

Tel: +86-510-85311707, 85310593

Fax: +86-510-85310726

Date Prepared: May 22,2012

2. Device Name: SonoTouch Series Diagnostic Ultrasound System

Common/Usual Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II

Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

2. Marketed Device:

K102256, GE LOGIQ e Ultrasound System

3. Device Description:

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The SonoTouch Series device is a compact and extremely portable ultrasound system consisting of a hand-carried console with the ability to dock it with a Docking station or mobile Docking cart. The primary means of control is graphical user interface implemented by a touch sensitive screen over the color LED display providing additional command input and keyboard entry. It utilizes interchangeable electronic-array transducers operating B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, or a combination of these modes, with digital acquisition, processing and display capability operating under a Linux OS. Powered by an integrated battery or from a separate power supply in the docking station or docking cart, the SonoTouch Series is used primarily where portability, size and convenience are TERMOREMENT ಸ್ವಾಚಲಿಗಳು ಆಚರಿಗು.

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essential.

The SonoTouch Series Models, have been designed to meet the following product safety standards: NEMA UD 2, NEMA UD 3, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC 10993-1.

4. Indications for Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

Comparison to Predicate Device:

The SonoTouch Series Models is of comparable type and substantially equivalent to the GE LOGIQ i, LOGIQ e, Vivid e Diagnostic Ultrasound(K102256). All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have the same intended uses and basic operating modes as the predicate device. All systems allow for specialized measurements of structures and flow, and calculations.

5. Conclusion:

The SonoTouch Series Models is substantially equivalent in safety and effectiveness to the predicate systems. The systems are intended for diagnostic ultrasound imaging and fluid flow analysis. The systems have the same gray-scale. The systems have acoustic output levels below the applicable FDA limits. The systems are designed to applicable electrical and physical safety standards.

End of 510(k) Summary.

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Page 1 of 3 Page 2 of 2



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

AUG 2 2012

CHISON Medical Imaging Co., Ltd. % Mr. Michael S. Ogunleye Third Party Program Manager/Lead Medical Auditor TUV Rheinland of North America 12 Commerce Road NEWTOWN CT 06470

Re: K121867

Trade/Device Name: SonoTouch Series Diagnostic Ultrasound Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 25, 2012 Received: July 25, 2012

Dear Mr. Ogunleye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoTouch Series Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

C3, Convex Array
MC3, Micro-convex Array
V6, Micro-convex Array
L7M, Linear Array
L7S, Linear Array

R7, Linear Array
L7L, Linear Array
P3, Phased Array
MC5V, Convex Array
MC6, Convex Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris

Acting Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

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Diagnostic Ultrasound Indications For Use

1.3 Indications for Use

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

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Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

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Diagnostic Ultrasound Indications For Use

System:

SonoTouch Series Diagnostic Ultrasound Systems

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation							
		<u> </u>							
General	Specific	В	M	PWD	CWD	Color	Power	Other*	
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Amplitude)	Combined	
0.141.1.1	0.1.1.1.		├—				Doppler		
Ophthalmic	Ophthalmic		 		·				
Fetal Imaging &	Fetal	N	N	N		N-	N	Note 1	
Other	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)				·				
	Laparoscopic							·	
	Pediatric	Ν	N	N		N	N	Note 1	
,	Small Organ ^[1] (Specify)	Z	N	N	-	N	N	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	
	Trans-vaginal	Ν	N	N		N	N	Note 1	
	Trans-urethral	-							
	Trans-esoph. (non-Card.)							····	
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	
! 	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	
	Intravascular								
	Other (Urology)	N	N	N		N	N	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	
	Intravascular (Cardiac)	•						110101	
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)					_		!	
Peripheral Vessel		N	N	N		N	N	Note 1	
	Other (Specify)							1010 1	
NT	indication: P = previously clear	- 11		<u> </u>			n this same di		

	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)					<u> </u>		
N = new	indication; P = previously clea	red b	y FD	A;	E = a	added und	er this append	ix
Note 1: B+M, B+1	PWD, B+Color Doppler, B+Powe	r Dog	pler,	B+Col	lor Doppl	er+PWD.	B+Power Dor	poler+PWD
Comments:	• • •	-	•					· • · · · · · ·
Small Organ: Thy	roid, testes and breast							
Additional Comn						 	<u></u>	
Prescription Use	1		AND	OR.			Over-The-Coun	ter Use
(Part 21 CFR 801 S	ubpart D)						(21 CFR 801	Subpart C)
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Indications For Use

Page 2 of 12

SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

C3, Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cl	inical Application	Mode of Operation							
			[
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	
Ophthalmic	Ophthalmic			-					
Fetal Imaging &	Fetal	Ν	N	N		N	N	Note 1	
Other	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	
	Small Organ ^[1] (Specify)		<u> </u>						
	Neonatal Cephalic								
	Adult Cephalic		<u> </u>					<u> </u>	
	Trans-rectal			ļ					
	Trans-vaginal								
	Trans-urethral							ļ	
	Trans-esoph. (non-Card.)		<u>L</u>			1			
	Musculo-skeletal (Conventional)		<u> </u>	<u> </u>					
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Urology)	N	N	N		N	N .	Note 1	
	Other (Ob/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult		<u> </u>			<u> </u>	<u> </u>		
	Cardiac Pediatric							<u>.</u>	
	Intravascular (Cardiac)	<u> </u>	ļ					ļ	
1	Trans-esoph. (Cardiac)			<u> </u>				<u></u>	
	Intra-cardiac		<u> </u>					<u>.</u>	
	Other (Specify)		1		<u> </u>	<u> </u>			
Peripheral Vessel	Peripheral vessel		<u> </u>		<u> </u>			ļ <u>.</u>	
	Other (Specify)		<u>L</u>	<u> </u>			er this append		

N = new indication; P = previously cleared by FDA;E = added under this appendixNote 1 B+M B+PWD B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Comments:	, 2	11
Small Organ: Thyroid, testes and breast		
Additional Comments:		
Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)
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Indications For Use

SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

MC3, Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined		
Ophthalmic	Ophthalmic						,			
Fetal Imaging &	Fetal		<u> </u>							
Other	Abdominal	N	N	N		N	N	Note 1		
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
. •	Pediatric		L							
	Small Organ ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)							·		
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)		,							
	Intravascular									
	Other (Urology)									
	Other (Ob/GYN)		,							
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1		
	Cardiac Pediatric	N	N_	N		N	N-	Note 1		
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac				-					
	Other (Specify)									
Peripheral Vessel	Peripheral vessel									
	Other (Specify)									

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD Comments:

Small Organ: Thyroid, testes and breast

Additio	nal	Comn	nents:

Prescription Use	, AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)
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Indications For Use

Page 4 of 12

SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

V6, Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CP!!1 A1!4!			Mode of Operation							
Ci	inical Application	<u> </u>		1	Mod	ie of Opera	le of Operation			
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined		
Ophthalmic	Ophthalmic									
	Fetal	N	N	N		N	N	Note 1		
Other	Abdominal									
	Intra-operative (Specify)		<u></u>					•		
	Intra-operative (Neuro)		<u> </u>							
	Laparoscopic]						
	Pediatric									
	Small Organ ^[1] (Specify)									
	Neonatal Cephalic		<u> </u>							
	Adult Cephalic									
	Trans-rectal	Ν	N.	N		N	N	Note 1		
	Trans-vaginal	N	N	N		N	N	Note 1		
	Trans-urethral		<u> </u>							
	Trans-esoph. (non-Card.)		<u> </u>							
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular									
	Other (Urology)	Ν	N	N		N	N	Note 1		
	Other (Ob/GYN)	Ν	N	N		N	N	Note 1		
Cardiac	Cardiac Adult						,			
Ì	Cardiac Pediatric						<u> </u>			
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)	·								
	Intra-cardiac									
	Other (Specify)							•		
Peripheral Vessel	Peripheral vessel		<u>L.</u>							
	Other (Specify)	l	<u> </u>			<u>L</u>		<u> </u>		

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Small Organ: Thyroid, testes and breast

N = new indication;

Additional Comments:

Comments:

 AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

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510k Section 1.3

Indications For Use

P = previously cleared by FDA;

Page 5 of 12

E = added under this appendix

SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

L7M, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation							
				•					
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal								
Other	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
,	Pediatric	Z	N	N		N	N	Note 1	
	Small Organ ^[1] (Specify)	Ζ	N	N		N	N	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Ν	N	N		N	N ·	Note 1	
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	
	Intravascular			1					
	Other (Urology)	, ,							
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	Ν	N	Ν		N	N	Note 1	
	Other (Specify)								

·		
Note 1: B+M, B+PWD, B+Color Doppl	er, B+Power Doppler, B+Color Doppl	er+PWD, B+Power Doppler+PWD
Comments:	·	
Small Organ: Thyroid, testes and breast	t ·	
Additional Comments:		
Prescription Use	. AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)
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SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

L7S, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cl	inical Application	Mode of Operation							
						ļ			
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal								
Other	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic						,		
	Pediatric	2	N	N		N -	N	Note 1	
	Small Organ ^[1] (Specify)	Z	N	N		N	N	Note 1	
,	Neonatal Cephalic			<u> </u>					
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal].	·	
	Trans-urethral					_			
	Trans-esoph. (non-Card.)]					
	Musculo-skeletal (Conventional)	Z	N	N		N	N	Note 1	
	Musculo-skeletal (Superficial)	Z	N	N		N	N	Note-1	
	Intravascular								
	Other (Urology)				:				
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric							,	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)							ļ	
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	
	Other (Specify)								

Note 1: B+M, B+PWD, B+Color Dopp	ier, B+Power Doppler, B+Color Doppler	r+PWD, B+Power Doppler+PWD
Comments:		
Small Organ: Thyroid, testes and breas	at .	
Additional Comments:		
Prescription Use <u>√</u>	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)
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SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

R7, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
			<u> </u>							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other* Combined		
Ophthalmic	Ophthalmic									
Fetal Imaging &	Fetal									
Other	Abdominal									
	Intra-operative (Specify)		<u>.</u>	ļ, i						
	Intra-operative (Neuro)									
	Laparoscopic							-		
	Pediatric		i							
	Small Organ ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	Z	N	N		N	N	Note 1		
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
·	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)		l							
	Intravascular	,								
	Other (Urology)	Z	N	N		N	N	Note 1		
	Other (Ob/GYN)		L							
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)		l			•				
	Trans-esoph. (Cardiac)									
	Intra-cardiac				·					
	Other (Specify)									
Peripheral Vessel	Peripheral vessel			ļ.,						
	Other (Specify)					1				

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Section 1.3

Indications For Use

Page 8 of 12

SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

L7L, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined			
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal		•								
Other	Abdominal										
	Intra-operative (Specify)		L								
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	N	N	Ν		N	N	Note 1			
	Small Organ ^[1] (Specify)	N	N	Ν		N	N .	Note 1			
	Neonatal Cephalic		[. <u>.</u>								
	Adult Cephalic										
	Trans-rectal							-			
	Trans-vaginal										
•	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1			
	Musculo-skeletal (Superficial)	Ν	N	N		N	N	Note 1			
	Intravascular										
	Other (Urology)										
	Other (Ob/GYN)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
i	Trans-esoph. (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1			
	Other (Specify)		<u> </u>								

N = new indication;P = previously cleared by FDA;

E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppl Comments: Small Organ: Thyroid, testes and breast Additional Comments:	er, B+Power Doppler, B+Color Doppler	-PWD, B+Power Doppler+PWD
Prescription Use <u>√</u> (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use(21 CFR 801 Subpart C)
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SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

P3, Phased Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
,										
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined		
Ophthalmic	Ophthalmic				İ					
Fetal Imaging &	Fetal									
Other	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)					•				
	Laparoscopic									
	Pediatric									
	Small Organ ^[1] (Specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
·	Trans-urethral							•		
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)]						
	Musculo-skeletal (Superficial)			}						
	Intravascular						·			
	Other (Urology)									
, 	Other (Ob/GYN)		1	ļ						
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1		
	Cardiac Pediatric	Ν	N	N	N	N	N	Note 1		
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral Vessel	Peripheral vessel									
	Other (Specify)									

y cicalcu by 1 DA,	E - added under tills appendix	
-Power Doppler, B+Co	olor Doppler+PWD, B+Power Doppler+PV	VĽ
	_ .	
AND/OR	Over-The-Counter Use	
	(21 CFR 801 Subpart 6	C)
		_
ce of CDRH, Office of Device Evalua	ation (ODE)	
	-Power Doppler, B+Co AND/OR THIS LINE-CONTINU	-Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PW

Section 1.3

SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

MC5V, Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
	·							,		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined		
Ophthalmic	Ophthalmic		<u> </u>							
Fetal Imaging &	Fetal		<u> </u>	ļ						
Other	Abdominal	Ν	N	N		N	N .	Note 1		
	Intra-operative (Specify)					<u> </u>				
	Intra-operative (Neuro)		ļ							
	Laparoscopic									
	Pediatric	N	N	N		N	N	Note 1		
	Small Organ ^[1] (Specify)			ļ.,						
	Neonatal Cephalic			<u> </u>						
	Adult Cephalic		<u> </u>	<u> </u>						
	Trans-rectal		<u> </u>	<u> </u>						
	Trans-vaginal			ļ <u> </u>						
	Trans-urethral			<u></u>						
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular									
	Other (Urology)									
	Other (Ob/GYN)	<u> </u>	L							
Cardiac	Cardiac Adult			<u> </u>						
	Cardiac Pediatric	N	N.	N		N	N	Note 1		
	Intravascular (Cardiac)			<u> </u>						
	Trans-esoph. (Cardiac)									
	Intra-cardiac		<u> </u>	<u></u>				-		
	Other (Specify)		ļ							
Peripheral Vessel	Peripheral vessel									
	Other (Specify)									

Other (Spe	cify)						
N = new indication;	P = previously clea	ared by	FDA;	$\mathbf{E} = \mathbf{a}$	dded unde	er this appendi	ix
Note 1: B+M, B+PWD, B+C Comments: Small Organ: Thyroid, testes Additional Comments:	** ,	er Dopp	oler, B+Col	or Doppl	er+PWD,	B+Power Dop	pler+PWD
Prescription Use		A	ND/OR		(Over-The-Coun (21 CFR 801	
	WRITE BELOW THIS	LINE-	CONTINUE	ON ANO	THER PA	•	
11.1.107	Concurrence of CD	RH, Office	of Device Evaluat	ion (ODE)			

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Division of Radiological Devices

nk (2) 867

SonoTouch Series Diagnostic Ultrasound Systems

Transducer:

MC6, Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD .	Color Doppler	Power (Amplitude) Doppler	Other* Combined			
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal			<u> </u>							
Other	Abdominal	Ν	N	N		N	N	Note 1			
	Intra-operative (Specify)										
	Intra-operative (Neuro)										
	Laparoscopic			<u> </u>							
	Pediatric	2	N	N		N	N N	Note 1			
	Small Organ ^[1] (Specify)	Z	N	N		N	N	Note 1			
	Neonatal Cephalic			Ĺ		<u> </u>					
	Adult Cephalic			<u></u>							
	Trans-rectal						·				
	Trans-vaginal					<u> </u>	<u> </u>				
·	Trans-urethral										
	Trans-esoph. (non-Card.)							<u> </u>			
	Musculo-skeletal (Conventional)										
	Musculo-skeletal (Superficial)							•			
	Intravascular		[
	Other (Urology)										
	Other (Ob/GYN)		Ĺ								
Cardiac	Cardiac Adult				ļ	'	ļ				
	Cardiac Pediatric	N	N	N	<u>. </u>	N	N	Note 1			
	Intravascular (Cardiac)		<u> </u>								
İ	Trans-esoph. (Cardiac)		<u> </u>								
	Intra-cardiac										
	Other (Specify)			}		-					
Peripheral Vessel	Peripheral vessel	N	N	N	ļ	N	N	Note 1			
	Other (Specify)			<u> </u>		11 1					

Other (Specif	·y)	11				
N = new indication;	P = previously clea	red by FD	A;	E = added	under this append	lix
Note 1: B+M, B+PWD, B+Cold Comments: Small Organ: Thyroid, testes ar		er Doppler,	B+Color D	oppler+PV	/D, B+Power Do	oppler+PWE
Additional Comments:	<u> </u>		<u></u>			
Prescription Use		AND	OR		Over-The-Cou (21 CFR 80)	
(Part 21 CFR 801 Subpart D)						
(PLEASE DO NOT V	IRITE BELOW THIS	LINE-CON	<u>ITINUE ON</u>	ANOTHER	<u>PAGE IF NEEDI</u>	±D}
	Concurrence of CDI	RH, Office of Dev	ice Evaluation (O	DE)		

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